REMARKS

Claims 5, 9-10, 12-14, 19-21, 39, and 50 are pending in the present application. Claims 6-8, 11, 15-18, 42, 46, and 47 have been cancelled. Claims 5, 9, 10, 12, and 20 have been amended. Claim 50 has been added. Support for claim 50 can be found on page 72 line 29 through page 73 line 4. No new matter has been introduced. The claims have been rejected for lack of clarity, lack of utility, and lack of enablement.

INFORMATION DISCLOSURE STATEMENT

The Examiner has stated that the Information Disclosure Statement was filed in January 2002, but was not found in the USPTO file. The Examiner has requested a duplicate copy of said filing. Applicants will prepare and submit the appropriate Information Disclosure Statement under separate cover.

SPECIFICATION

The Examiner has stated that the disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant has deleted embedded hyperlinks from the disclosure through above amendments to the specification. Replacement paragraphs have been provided accordingly in this document and no new matter has been added.

CLAIM REJECTIONS

Rejections under 35 U.S.C.§ 112, second paragraph

Claims 5-14 have been rejected under 35 USC § 112, second paragraph as being vague and indefinite. Applicants disagree.

Examiner alleges that (a) recitation of "a mature form ... SEQ ID NO: 13," (claim 5(a) and 5(b)) is vague and indefinite because the instant application does not identify the mature forms of the polypeptide mentioned in the claim; (b) parts (e) and (f) of claim 5 do not make sense because the preamble and embodiments are not in agreement; and (c) the recitation of the term "allelic" is vague and indefinite because the application does not disclose the genetic locus of the sequence in the claim. Applicants have amended claims 5, 9, and 12-14, and canceled claims 6-8, 11 and therefore submit that this rejection is now moot and should be withdrawn.

Rejections under 35 U.S.C. § 101

Claims 5-14, 19-21, 39, 42, 46, and 47 have been rejected under 35 U.S.C. § 101 as allegedly lacking support by a specific, substantial, and credible utility. The Examiner alleges that the list of uses on pages 3 and 6-9 of the instant application cannot substitute for a patentable utility. Applicants have canceled claims 6-8, 11, 15-18, 42, 46, and 47. Thus, this rejection, as it refers to these claims, is moot and should be withdrawn. Applicants disagree that this rejection applies to pending claims 5, 9, 10, 12, 13, 14, 19-21, and 39.

The Examiner's attention is directed to the Manual of Patent Examination Practice (MPEP) 8th edition, section 2100 which states that only one credible assertion of specific and substantial utility need be specified for an invention:

> Specific Utility
>
> A "specific utility" is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear the "useful" invention may arise from what has been disclosed by the applicant *Knapp v. Anderson,* 477 F. 2d 588, 177 USPQ 688 (CCPA 1973).

Substantial Utility

> A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay, that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition, would also define a "real world" context of use in identifying potential candidates for preventative measures or further monitoring. Section 2107.01

Applicants submit that at least one substantial and specific utility exists for the claimed invention and is readily apparent based on the teachings of the specification. Applicants respectfully assert that the claimed nucleic acid encoding the polypeptide, SEQ ID NO: 13, is useful in distinguishing between tissue types, such as kidney cancer tissue from normal tissue, shown in the specification (See for example, Example 2, NOV4) beginning on page 237, line 17 through page 255 line 33). The RTQ-PCR expression pattern demonstrates that expression of NOV4 is expressed more highly in normal kidney tissues than in kidney cancer tissues. These results demonstrate that the expression of nucleic acid encoding the polypeptide of SEQ ID NO: 13 is distinctly different in these two tissues. Therefore, one of skill in the art would utilize the nucleic acid encoding the polypeptide SEQ ID NO: 13 for example, as a marker for kidney cancer. The nucleic acid encoding the polypeptide SEQ ID NO: 13 can also be used in screens for effective therapeutics that modulate the activity, latency or predisposition to cancerous conditions. (for example, kidney cancer). (*See* specification page 237, line 18 through page 255 line 33). The function of distinguishing between tissue types demonstrates a "real world" use and patentable utility. Applicants assert that the specification identifies that the differential expression of 105827550_EXT allows for distinction between tissue types.

Consistent with the teachings of the specification Applicants respectfully submit that it would be clear to the skilled artisan that the nucleic acid encoding the polypeptide of the present invention (SEQ ID NO: 13) is useful as a marker or to distinguish between tissues such as those of the normal kidney and kidney cancer, and thus has a credible, specific, and substantial utility. Therefore, Applicants respectfully request withdrawl of the rejection under 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 112, first paragraph

Enablement Rejection

Claims 5-14, 19-21, 39, 42, 46, and 47 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that one skilled in the art would not know how to make and/or use the invention. As discussed above, Applicants have canceled claims 6-8, 11, 15-18, 42, 46, and 47. Thus, this rejection, as it refers to these claims, is moot and should be withdrawn. Applicants disagree that this rejection applies to pending claims 5, 9, 10, 12, 13, 14, 19-21, and 39. Claims 5, 9, 10, 12, 13, 14, 19-21, and 39 have a specific, substantial, and credible utility as discussed above. Because these claims do have at least one specific, substantial, and credible utility,(for example, more specifically, the ability to differentiate between normal and cancerous kidney tissues,) Applicants submit that this rejection should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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